Risk Reduction for Methylene Chloride and N-Methylpyrrolidone (NMP) in Paint and Coating Removal under the Toxic Substances Control Act (TSCA)

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Background: TSCA Work Plan for Chemical Assessments

- EPA has identified a subset of existing chemicals as a high priority for risk assessment
- 2012-2013:
  - With input from stakeholders, EPA identified a subset of chemicals for assessment, known as the TSCA Work Plan, and described the methodology for how they were prioritized
  - Performed problem formulation for five Work Plan chemicals, developed draft risk assessments for peer review, and released them for public comment.

Background: TSCA Work Plan for Chemical Assessments

- 2014-2015:
  - Released first final risk assessments (TCE, methylene chloride, NMP, antimony trioxide, HHCB)
    - No risks found for uses assessed for antimony trioxide and HHCB.
    - Risks found for uses assessed for TCE, methylene chloride, and NMP. Risk management process began.
  - Refreshed Work Plan with updated exposure information; currently contains 90 chemicals
- 2015-2016:
  - Problem formulation and data needs assessment issued for several flame retardant clusters
  - Problem formulation issued for 1,4-Dioxane
  - Draft risk assessment for 1-bromopropane released for public comment
- June 22, 2016:
  - TSCA amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

Toxic Substances Control Act (TSCA)

- TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, authorizes EPA to move ahead with ongoing efforts to issue section 6(a) rules for TSCA Work Plan chemicals with completed risk assessments published prior to enactment.
- TSCA section 6(a) provides EPA with the authority to prohibit or limit the manufacture, processing, distribution in commerce, use or disposal of a chemical or mixture.
  - EPA must:
    - Determine after risk evaluation whether a chemical substance or mixture "presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation….under the conditions of use."
    - Apply one or more of the regulatory options to the extent necessary so that the chemical substance no longer presents such risk.

Methylene Chloride and NMP: Proposed Regulation

- EPA plans to propose a regulation under TSCA § 6(a) to reduce or eliminate risks posed by methylene chloride and NMP in commercial and consumer paint and coating removal
  - Examples of commercial use and occupational exposures:
    - Automotive, aircraft, and marine craft body paint, and interior repair and maintenance
    - Flooring contractors
    - Furniture repair and refinishing
    - Painting and wall covering contractors
    - Bathtub refinishing
  - Examples of consumer use:
    - Do-It-Yourself projects, such as furniture refinishing and home renovations
    - Other consumer projects (boats, small aircraft, cars)
    - Graffiti removal from private property

Overview: Methylene Chloride and NMP

- EPA assessed Methylene Chloride and NMP paint removal uses as part of the TSCA Work Plan for Chemical Assessments.
- Methylene Chloride
  - Volatile, colorless liquid, non-flammable, non-explosive, non-corrosive, inexpensive.
  - Used frequently as a solvent; also in adhesives, metal cleaning, chemical processing, pharmaceuticals.
  - 25% of methylene chloride in the US used in paint removers (66.3 million lbs annually), down from 50% in 1980s.
- NMP
  - Mildly volatile, colorless liquid, low flammability, non-explosive.
  - Used frequently as a solvent; also in adhesives, leather and brush cleaners, manufacturing of circuit boards, pesticides, petrochemical processing.
  - 9% of NMP in the US used in paint removers (16.6 million lbs annually).
  - Frequently an alternative to methylene chloride paint removers.

Paint Removal Scenarios EPA Assessed

- Paint removal can be performed for a variety of activities:
  - Bathtub refinishing
  - Automotive refinishing
  - Art restoration and conservation
  - Aircraft paint stripping
  - Ship paint stripping
  - Graffiti removal
  - Home refinishing of wood structures and flooring
- Paint removal can be conducted by **commercial (occupational)** or **consumer** users

Risk Assessment: Methylene Chloride

- Final TSCA Work Plan Chemical Risk Assessment: August 2014
  - Followed Agency peer review process of publishing a public draft, peer review, and response to peer review and public comment
- Risk assessment identified inhalation risks from paint removers containing methylene chloride:
  - Chronic exposure effects: cancer and liver toxicity
  - Acute exposure effects: Neurotoxicity - confusion, incapacitation, and death
  - Risks from chronic (lifetime) exposure in majority of scenarios except when personal protective equipment (respirator) is worn in low exposure scenarios.
  - Risks from acute high-end exposure (small, enclosed room with poor ventilation, such as a bathroom).
  - Risks to non-users (bystanders and adjacent workers) except in lowest exposure scenarios.
- See: http://www.epa.gov/assessing-and-managing-chemicals-under-tsca/assessments-tsca-work-plan-chemicals#dcm

Risk Assessment: Methylene Chloride

- Risks were identified for most worker and consumer exposure scenarios.
- For **non-cancer risks** a **margin of exposure** (MOE) method was used to determine the presence or absence of risk for both acute and chronic exposure scenarios.
  - The benchmark MOE used in the methylene chloride risk assessment is 10.
    - This benchmark constitutes 3x residual uncertainty in extrapolating from animals and 3X residual uncertainty for variability in humans
  - People exposed are considered to be at risk when MOEs are below the benchmark MOE of 10.
  - MOEs and risks calculations for non-cancer effects are on the next slide

- For **cancer risks**, the inhalation unit risk (IUR) was used to estimate excess cancer risks for inhalation occupational exposure scenarios.
  - The excess cancer risk is the product of the exposure concentration and the IUR
  - Protecting against non-cancer risks protects against these cancer risks
  - Risk calculations for cancer are shown on the next slide

Risk Assessment: NMP

- NMP is often marketed as a “safer” alternative to Methylene Chloride
- Final TSCA Work Plan Chemical Risk Assessment: March 2015
  - Followed Agency peer review process of publishing a public draft, peer review, and response to peer review and public comment
- Risk assessment identified dermal (liquid or vapor through skin) and inhalation exposure risks from the use of paint removers containing NMP:
  - Developmental effects (acute: fetal mortality; chronic: reduced fetal body weight). Concern is for women of child-bearing age.
  - Chronic exposure risks if used:
    - More than 8 hours per day for more than 5 consecutive days, even if specialized protective gloves are worn
    - More than 4 hours per day, for more than 5 consecutive days, if specialized protective gloves are not worn
  - Acute exposure risks if used:
    - More than 8 hours on a single day, even if specialized protective gloves are worn
    - More than 4 hours on a single day, if specialized protective gloves are not worn
  - No risks to bystanders
- See http://www.epa.gov/assessing-and-managing-chemicals-under-tsca/assessments-tsca-work-plan-chemicals#completed

Risk Assessment: NMP

- Risks were identified for a number of worker and consumer exposure scenarios.
  - No risks identified for workers or residents who may be located nearby those that are working with NMP-based paint removers.
- To determine the presence or absence of non-cancer risks for both **acute and chronic exposures**, the **margin of exposure** (MOE) method was used to evaluate the risk
  - The benchmark MOE used for the NMP risk assessment is 30.
    - This benchmark constitutes 3x residual uncertainty in extrapolating from animals and 10X residual uncertainty for variability in humans
  - All users exposed are considered to be at risk when MOEs are below the benchmark MOE of 30.

From Risk Assessment to Risk Reduction

Risks identified

- Methylene chloride and NMP found to pose risks when used in typical commercial and consumer scenarios

Risk reduction needed

- Methylene chloride: Exposures are 100 to 1,000 times greater than acceptable exposure levels
- NMP: Exposures are 5 – 10 times greater than acceptable exposure levels

Approach chosen

- Regulation by EPA under TSCA Section 6(a) is the approach most likely to reduce risks to workers and consumers

Options Under TSCA Section 6(a)

- Prohibit or restrict manufacture, processing or distribution in commerce.
- Prohibit or restrict for particular use or above a set concentration.
- Require minimum warnings and instructions.
- Require recordkeeping or testing by manufacturers and processors.
- Prohibit or regulate manner or method of commercial use.
- Prohibit or regulate manner or method of disposal.
- Direct manufacturers/processors to give notice of the determination of risk to distributers and users and replace or repurchase.

EPA's Authority to Regulate These Risks

- OSHA authority extends only to private sector employers; CPSC authority extends only to consumer products
- EPA is working closely with OSHA and CPSC; both agencies agree that TSCA is the appropriate authority to address the risks that EPA has identified, including those that occur in workplace, because TSCA authority can address risks that cut across worker, public sector and consumer settings
- TSCA restrictions are consistent with OSHA hierarchy of hazard control (eliminate/substitute hazard; engineering controls; best practices administrative controls; personal protective equipment)

Developing Potential Regulatory Options

- Over the past year, EPA has been working to identify regulatory options under Section 6(a) of TSCA that would reduce the risks identified to benchmark levels
- In addition to other Federal agencies, we've been working with our stakeholders, including:
  - Affected States and Tribes
  - Chemical manufacturers, product formulators, and their trade associations
  - Commercial paint remover users in various sectors
  - Small businesses

Substitute Chemicals and Alternative Methods

- EPA has learned about successful use of substitute chemicals and alternative methods for many types of paint and coating removal with methylene chloride or NMP
  - Chemical substitutes include: Benzyl alcohol, dibasic esters, acetone-toluene-methanol formulations, and caustics
  - Alternative processes include: Heat guns, mechanical sanding, hydroblasting, media blasting (starch, soda, etc)
- Generally, hazards of substitute chemicals or alternative methods are of less concern
- Information on successful substitutes was obtained from public reports, presentations at conferences, industry research and ongoing discussions with stakeholders

Developing Potential Regulatory Options

- What we've heard from stakeholders, from industry research, and during our consultations:
  - Marinecraft:
    - Paint is generally not removed to the substrate; when needed, sand or soda blasting are used.
    - Chemical stripping requires consideration of disposal (heavily regulated near water).
  - Aircraft:
    - Use of methylene chloride is declining, particularly among large scale users, due to air regulations and other considerations.
    - Refinishing of small aircraft still use methylene chloride, though many now use benzyl alcohol formulations.
  - Renovations and contractors:
    - Many firms have stopped using methylene chloride due to worker safety concerns, potential for fatal accidents, odor (employee and client complaints), and specialized PPE, training, and waste disposal needed.
    - Some firms use methylene chloride only outdoors or with fans for ventilation
    - Alternatives identified tend to be mechanical methods or benzyl alcohol; alternatives can take longer than methylene chloride to complete a job.
    - Certain wood substrates can be damaged by mechanical methods and require chemical stripping.
  - Automotive (collision repair and autobody):
    - Chemical removers do not appear to be critical for this sector as industry reps reported large use of abrasives for paint removal.
  - Furniture refinishing:
    - Seem to exclusively use methylene chloride, with some attempts at alternatives containing acetone.
    - There are flammability concerns with substitutes given the prevalence of wood substrates.
    - Certain wood substrates can be damaged by mechanical methods and require chemical stripping.

Next Steps and Your Feedback

- Planning to publish the proposed rule later this year
- We would like to hear more about:
  - Your experiences with methylene chloride or NMP
  - Exposure reduction for workers for these types of chemicals
  - Experiences with alternatives for paint and coating removal
- Do you have any advice for EPA?

Contact Information

- For paint removers:
  - Niva Kramek, 202-564-2897, kramek.niva@epa.gov

- All Work Plan Chemical risk assessments: http://www.epa.gov/assessing-and-managing-chemicals-under-tsca/assessments-tsca-work-plan-chemicals
- Changes to TSCA:

https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act